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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	Edward N. Barthell	Art Unit:	3626
Serial No.:	10/649,127	Examiner:	Sheetal Rangrej
Filing Date:	August 27, 2003	Conf. No.:	4764
Title:	*Bio-Surveillance System and Method*		

SUPPLEMENTAL DECLARATION UNDER 37 C.F.R. § 1.131

Commissioner For Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

I, Edward N. Barthell, MD, declare:

1. I am the inventor of the subject matter of the above-identified U.S. Patent Application ("the invention").

2. I have reviewed the claims of this Application.

3. I conceived in the United States, prior to March 26, 2002, the filing date of U.S. Published Patent Application No. 2003/0187615 and entitled *Methods and Apparatus for Early Detection of Health-Related Events in a Population*, the invention as set forth in the aforementioned claims.

4. The following facts and evidence are submitted in support of this declaration in addition to the facts and evidence previously provided in the Declaration filed March 17, 2007 in the above-captioned matter with the United States Patent and Trademark Office.

5. In 2002, the assignee, Infinity Healthcare, was a very small physician staffing company with limited early experience with technology development and no full time employees working on intellectual property issues. The "Frontlines of Medicine" or simply "Frontlines" project serving as the basis of the invention was manned solely by myself and a few other physicians working on a volunteer basis. We were full time emergency care clinicians and had only limited time to devote to the Frontlines project.

6. Nevertheless, between March 26, 2002 and July 26, 2002, I worked diligently to refine the invention to the point that I felt it was ready for patenting. For instance:

A. Before March 26, 2002, and from March 26, 2002 to April 28, 2002, I diligently collaborated in planning, organizing and managing a consensus conference the goal of which was to develop a consensus for standardized tools and procedures for reducing to practice the Frontlines concept that I had previously conceived. I felt that developing these standardized tools with input from third parties was critical in launching an effective bio-surveillance system while developing a spirit of collaboration from all aspects of the emergency medical community. My efforts are described in some detail in a September, 2004 Annals of Emergency Medicine article co-authored by me and entitled "The Frontlines of Medicine Project Progress Report: Standardize Communication of Emergency Department Triaged Data for Syndromic Surveillance." A copy of that article is attached to this declaration as Appendix A

1. In preparation for the consensus conference, eight other emergency care physicians and I each solicited feedback from 3-5 other individuals believed to have experience in fields

relating the Frontlines project. We set a deadline of April 15, 2002 for the delivery of that feedback. We used the feedback to our solicitation to set an agenda for the consensus conference.

2. I also participated in the development of a rank order of process for the creation of a list of 60 participants for the consensus conference and in sending out the invitations. I also participated in developing an agenda for the consensus conference and arranged for the speakers.

3. I attended the consensus conference on April 28, 2002. I provided the introductory presentation and served as the primary moderator of the other speaker presentations.

B. From April 29, 2002 to on or about July 16, 2002, I participated in diligently evaluating the results from the consensus conference and in establishing a priority to further define data elements to be included in a standardized triage surveillance report of the present invention and to define a preferred list of codified values to be used to categorize triage chief complaints. Specifically:

1. A survey process was performed to define (1) elements to be included in a standardized emergency medicine surveillance triage report message; and (2) a preferred set of ICD-9 coded values for the chief complaint element within the triage message report.

2. Upon completion of the survey process, I participated in the performance of a retrospective analysis in an initial validation test of the chief complaint list. The goal was to

determine whether text-based complaint could be successfully categorized into the complaint list with high interrater reliability. This required the compilation of text-based complaints from three hospitals to create a consecutive series of 1000 text-based chief complaints. The details of this validation testing are described on page 249 Appendix A.

3. During the time of the survey and the retrospective analysis I decided, on or about July 16, 2002, that the invention was sufficiently refined to proceed with the preparation of a United States patent application.

7. From on or about July 16, 2002 to October 11, 2002, I diligently worked with my attorneys to evaluate the potential patentability of my invention to prepare and file a patent application.

A. During the evaluation process described in paragraph 6(B) above, I became aware that a company called IBEX was alleged to have a pending patent application for a bio-surveillance system. I commissioned my patent attorney, Mr. Timothy Newholm, to check into possible patents or published patent applications to IBEX.

B. On July 23, 2002, I participated in a teleconference which Mr. Newholm, who informed me that he had been unable to locate any published patent applications or issued patents to IBEX. Mr. Newholm will also inform me of the procedures for evaluating the patentability of an invention and for preparing and filing a patent application during that teleconference, and we scheduled a personal meeting for July 31, 2002.

C. I met with Mr. Newholm on July 31, 2002 to provide him with the information needed to perform a patentability search and analysis.

D. On or about August 27, 2002, I received a packet of information from Mr. Newholm. That packet included a nine page letter and over 30 documents describing other bio-surveillance initiatives.

E. As time permitted from on or about August 27, 2002 to about the third week in September 2002, I evaluated the results of Mr. Newholm's report. Upon reading his report and other documents cited in it, I became convinced that my invention was patentable. I contacted Mr. Newholm on or about the third week of September, 2002 and authorized him to proceed with the preparation of a provisional patent application, which I understand was filed by Mr. Newholm on October 11, 2002.

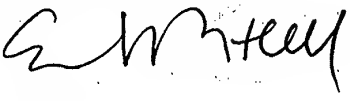
8. Simultaneously with other activities referenced in paragraphs 6 and 7 above, I worked toward establishing pilot programs to field test the invention or at least aspects of it. For example, I participated in the development and implementation of a bio-surveillance system for the City of Milwaukee Public Health department that was employed during the Major League Baseball All-Star Game and surrounding events, which took place on July 9, 2002. I also participated in the development of several versions of various-size pilot plans and the submission of these pilot plans potential funding agencies.

9. During the entire period referenced above, I remained employed as a full-time emergency medical clinician. While my other obligations prevented me from working on the Frontlines project continuously during that period, I do not believe that, except for time periods when I was waiting on results from others, such as the periods

during which Mr. Newholm was performing his patentability search and analysis and was preparing a patent application, no more than a few days went by without me making some efforts to refine the invention to the point I felt that it was ready for patenting.

10. I declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Respectfully submitted,



Edward N. Barthell, MD

The Frontlines of Medicine Project Progress Report: Standardized Communication of Emergency Department Triage Data for Syndromic Surveillance

Edward N. Barthell, MD, MS
Dominik Aronsky, MD, PhD
Dennis G. Cochrane, MD
Greg Cable, PhD
Thomas Stair, MD
For the Frontlines Work Group*

From the Department of Emergency Medicine, St. Mary's Hospital Ozaukee, Mequon, WI (Barthell); the Department of Emergency Medicine, Medical College of Wisconsin, Milwaukee, WI (Barthell); the Department of Biomedical Informatics, Vanderbilt University Medical Center, Nashville, TN (Aronsky); the Department of Emergency Medicine, Morristown Memorial Hospital, Morristown, NJ (Cochrane, Cable); and the Emergency Medicine Residency Program, Brigham and Women's Hospital, Boston, MA (Stair).

**Members of the Frontlines Work Group are listed at the end of this article.*

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This article reports progress since the original publication of the Frontlines of Medicine Project. This project is a collaborative effort of emergency medicine (including emergency medical services and clinical toxicology), public health, other government agencies involved in health care and preparedness, law enforcement, and informatics to develop nonproprietary, standardized methods for reporting emergency department patient data. These data may be used for a variety of public health or clinical care initiatives, including syndromic surveillance for chemical and biological terrorism. This article reviews the outcome of the Project meeting in April 2002. Also, the article describes a Delphi Survey process to define the data elements in a triage surveillance report and to define a set of codified values for the chief complaint data element. An initial retrospective validation of the codified chief complaint values is provided, and prospective study of the proposed Frontlines' standards is encouraged.

[*Ann Emerg Med.* 2004;44:247-252.]

INTRODUCTION

This article reports progress since the original publication of the Frontlines of Medicine Project.[1] The Project conceptualizes the rapid deployment of a nonproprietary, vendor-neutral, regional public health information infrastructure, built using standards-based specifications for reporting and coding structures. This approach, resulting in interlinked regional public health networks, could be used as a surveillance system to potentially detect and, perhaps more important, assess and manage the medical response to chemical and biological terrorism.

The historical problems with effective collaboration between emergency medicine and public health, and the potential for improving the relationship in the future, were detailed in a review by Pollock et al.[2] Surveillance of diseases, injuries, and health risks was described as 1 of 4 major areas of emphasis. As part of a $1.1 billion federal program, in February 2002 the Centers for Disease Control and Prevention (CDC) required states to create work plans that met specific requirements. Two of the critical benchmarks were to develop a system to receive and evaluate urgent disease reports from all parts of state and local public health jurisdictions 24 hours a day, 7 days a week, and to develop a communications system that provides for a continuous flow of critical health information among hospital emergency departments (EDs), state and

local health officials, and law enforcement officials.[3] The Frontlines Project is intended to help pursue these benchmarks.

RELATED INITIATIVES

Given the new emphasis on surveillance and significant increases in funding, several relevant surveillance research projects, networking and communication efforts, and demonstration systems have begun to emerge since the original Frontlines article. The CDC has continued with the development of the National Electronic Disease Surveillance System. This public health initiative provides a standards-based, integrated approach to disease surveillance and attempts to connect public health surveillance to the burgeoning clinical information systems infrastructure.[4] Furthermore, the CDC has defined the Public Health Information Network as a crosscutting and unifying framework that is needed to better monitor a variety of data streams for early detection of public health issues and emergencies.[5] A number of states have received funding to implement the National Electronic Disease Surveillance System base system, including an integrated data repository and an ability to receive data from a variety of Web-based modules. The initial emphasis of the National Electronic Disease Surveillance System has been the electronic interchange of laboratory data, but planning for the future integration of emergency encounter surveillance data is beginning.

The Indianapolis Network for Patient Care in Indianapolis, IN, includes an automated transfer of data about reportable diseases from hospitals to public health authorities.[6] Researchers at Sandia National Laboratory have shown the feasibility of collecting emergency encounter data to detect 6 primary syndromes that might be consistent with bioterrorism,[7] and use of a Web-based surveillance system derived from an emergency triage log has been described.[8] Reis and Mandl[9] have shown how to use time series modeling to predict expected rates of emergency visits, which allowed them to then test the impact of various outbreaks and to detect an outbreak against the background "noise" pattern.

"Drop-in" surveillance is a term used to describe the application of syndromic surveillance systems for short periods, often a few weeks surrounding a significant event that is perceived to increase risk of a bioterrorism attack. Examples include the use of a CDC-designed system in New York City immediately after the September 11, 2001, attacks,[10] the Real-time Outbreak Detection System used during the Olympics in Utah,[11] and EMSystem used during the Summerfest music festival and the 2002 Major League Baseball All Star Game in Wisconsin.[12,13]

Although this type of "drop-in" system can be useful during high-profile events, the approach often requires clinical staff or other extra personnel to perform work that is not required for the routine day-to-day care of patients in the ED. As a result, resistance by busy ED staff and increased costs tend to limit the ability of this type of system to be sustainable for long periods. Therefore, research has continued on methods to collect data as a by-product of routine patient care, and the methods have been integrated with existing care processes. For example, the Real-time Outbreak and Disease Surveillance System laboratory at the University of Pittsburgh[14,15] now offers a number of public domain software tools to attempt to create a sustainable system that (1) extracts text-based chief complaints from hospital registration systems; (2) categorizes the complaints using a natural language process method; and (3) analyzes the data for trends.

THE FRONTLINES PROCESS AND METHODS

The Frontlines Project has developed further to conceptualize the development of an emergency medicine surveillance model best described as "interactive surveillance." In this model, a dynamic system is created that can adapt to evolving circumstances. Syndromic surveillance systems may set off an initial alarm because the prevalence of a condition exceeds expected thresholds (ie, the prevalence of patients with shortness of breath appears high). Public health authorities can then send dynamic electronic queries to emergency providers asking for more detailed data (eg, the prevalence of associated fever, hypoxia, history of toxic inhalation, or attendance at a public gathering, in patients presenting with shortness of breath). This method allows public health and emergency medicine to work together to rapidly determine whether a problem exists, what the nature of the problem is, and what its prevalence in the community is.

The initial Frontlines Project recommendations were developed according to a modification of the nominal consensus methods described by others[16] and structured to provide rapid cycles of feedback to rapidly deploy standardized tools. The Frontlines Work Group is composed of uncompensated volunteers with broad experience in informatics, emergency medicine, and disaster medicine. A rank order process was used to select 60 participants for a meeting that was held on April 28, 2002. On the basis of feedback obtained in response to the initial Frontlines article and during this meeting, a priority was

established to further define the data elements to be included in the standardized triage surveillance report and to define a preferred list of codified values to be used to categorize triage chief complaints.

Other authors have discussed the value of a standardized list of chief complaints to describe the reasons patients come to EDs. Aronsky et al[17] published a list of 57 chief complaints that were shown to be useful in codifying the reason for visit in 99% of cases after application of process control methods and education and feedback for triage staff. The Canadian Emergency Department Information System Working Group recently published version 1 of a presenting complaint list, which incorporates 18 major categories and 161 presenting complaints.[18]

The National Hospital Ambulatory Medical Care Survey[19] retrospectively analyzes emergency visits at a number of survey hospitals and categorizes the final diagnoses using *International Classification of Diseases, Ninth Revision (ICD-9)*[20] codes. The National Hospital Ambulatory Medical Care Survey uses a separate reason-for-visit categorization scheme that includes 162 reasons for visit arranged into 10 major systems and uses statistical extrapolation to determine the number and type of visits to EDs in the United States. Although *ICD-9* codes were intended primarily for diagnostic coding and are not always optimal for describing complaints, their widespread use and acceptance for other functions caused the Frontlines Project team to commit to using a subset of this coding system in creating a preferred list of chief complaint values.

Delphi Survey to Define Triage Elements

A Delphi Survey process was performed to define (1) a recommended set of data elements to be included in a standardized emergency medicine surveillance triage report message; and (2) a preferred set of *ICD-9* coded values for the chief complaint data element within the triage report message. The Delphi Survey process has been described.[21-23] A target acceptance rate of 75% was established in advance. Although researchers using Delphi Survey processes do not consistently agree on an appropriate target percentage, and some researchers define the target level during data collection, the 75% level was consistent with that established by others using the technique.

An initial Frontlines master complaint list was derived by Frontlines leaders from an examination of 4 other reference data sets, including a list provided by a multihospital emergency physician group billing department, the lists published by Aronsky et al[17] and the CDC National Hospital Ambulatory Medical Care Survey, as noted above, and a list provided by DSHI Systems (Rockledge, FL), a commercial provider of triage software. The Frontlines complaint list and the reference lists were circulated to all participants by electronic mail.

Twenty-eight participants reviewed the first round materials; 16 (57%) participants indicated acceptance of the initial specifications. According to the feedback received, a second round of revised materials was submitted to participants willing to proceed with further review. In the second round, 18 (86%) of 21 participants accepted the revised specifications.

Validation Testings Using Pooled Text-based Complaints

On completion of the survey process to define the triage surveillance report and the preferred values for chief complaint, a retrospective analysis was performed as an initial validation test of the chief complaint list. The goal was to determine whether text-based complaints could be successfully categorized into the Frontlines complaint list with high interrater reliability. We pooled text-based complaints from 3 hospitals located in eastern and Midwestern cities to create a consecutive series of 1,000 text-based chief complaints.

Two physicians categorized the text-based chief complaints into one of the Frontlines preferred values. (Available as Table E1 at http://www.mosby.com/AnnEmergMed.) When these 2 physicians did not agree, a third physician independently adjudicated the mapping to determine which category or categories of the Frontlines values would be considered a successful mapping of the text-based complaints. Eight staff members experienced in ED triage from 3 cities then independently categorized the consecutive text-based chief complaints into one of the Frontlines preferred values. The general instructions were to ask first "was the complaint caused by an injury," then "if no injury, was the complaint primarily pain," and if not, proceed to the system-based complaints.

After codifying the first 102 complaints, each rater was reviewed to be sure he or she understood and followed the general instructions. Each rater then categorized 898 consecutive complaints as test cases. The results were compiled and analyzed to determine the frequency with which each rater successfully categorized the text-based chief complaint as initially determined by the physicians.

RESULTS

The results of the Frontlines Delphi Survey process are the recommended data elements for the triage surveillance report and the preferred triage complaint categories as

[redacted] Table E1 and Figure E1 (available at [redacted].com/AmEmergMed). The data elements for the triage surveillance report include provider facility identification, patient identification, encounter identification, patient age, age unit, sex, date and time first documented in the ED, date and time of symptom onset, chief complaint, first ED responsiveness assessment, first ED systolic blood pressure, first ED diastolic blood pressure, first ED pulse rate, first ED temperature, ED temperature unit, and zip codes for home, work, and incident site. These data elements were defined using the same format used by the CDC in its descriptions of Data Elements for Emergency Department Systems.[24] The preferred chief complaint categories include 151 complaints arranged in 15 hierarchical categories.

Analysis of the retrospective evaluation showed that raters were unable to categorize the text-based complaints except by use of the "other complaint" category in 185 (2.6%) of 7,184 attempts. Overall, the 8 raters "successfully" categorized 6,334 (88.2%) of 7,184 text-based complaints according to the evaluation model we created. The individual rater success results ranged from 81.1% to 91.8%. A majority of raters (at least 4 of 7) were able to categorize the complaint to the "successful" category as defined by the physicians in 824 (91.8%) of 898 cases.

Because the Frontlines complaint categories are purposely focused on symptoms and not on diagnoses, problems with categorization seemed to occur when the text-based complaints were nonspecific or nonsensical (ie, "lung tr," "uro," "vg pn," "rt vein," or "crit eval") and when text-based complaints were focused on a specific diagnoses (ie, "cellulitis," "I think I have Lyme disease," or "my mother is having a stroke"; see Figure E1).

In an attempt to determine the interrater reliability of this exercise, we applied Cochran's Q statistic. The null hypothesis is that there is no difference among the 7 raters about correct mapping on these cases. We took a random sample of 100 from the list of 898 cases and calculated Cochran's Q statistic. The calculated value of Q for these data was 5.78 (df=6). Cochran's Q is distributed as a χ^2 statistic. We would have needed a calculated value of 12.59 or greater to reject this null hypothesis at 0.05. Therefore, we fail to reject the null and infer that the raters do not differ in this exercise.

DISCUSSION

The initial retrospective mapping of text-based chief complaints by the triage personnel yielded a high degree of interrater reliability but also demonstrated the limitations of this data source. Particularly if surveillance efforts are being made to detect cases that occur with relatively low frequency rates, the nonspecific and sometimes nonsensical nature of text-based chief complaints may lack utility.

We believe a prospective implementation of the use of Frontlines complaint categories would allow clinicians to better determine the appropriate category concurrently with the triage encounter, providing higher-quality data for subsequent surveillance, which is consistent with the Frontlines recommendation to pursue an interactive model of emergency medical surveillance whereby structured data are used to derive initial alerts of unusual events, and these alerts in turn activate messaging systems and lead to dynamic secondary queries to rapidly determine the cause of the observed unusual event.

We recognize several limitations associated with this work. Although we made every effort to systematically identify experts for contribution to our survey techniques, we realize that selection bias could have influenced our results. For example, we realized in retrospect that our group was underrepresented by pediatric emergency medicine specialists, who may have properly suggested some additional triage terms. Many of the participants had a particular interest in surveillance issues, so the selection of appropriate triage categories may have been affected by this interest, as opposed to participants with interests in other areas.

With regard to the mapping exercise results analysis, the κ statistic is often used in interrater reliability testing but is less useful in situations such as our exercise that involved such a large number of possible ratings and such a large number of raters. We acknowledge that future studies in this area may benefit by the application of alternative statistical techniques, such as a latent class concept that decomposes observed ratings into a class of systematically consistent and a class of fortuitous ratings.[25] We also acknowledge that our exercise could be criticized because we used a categorization by physicians as a "gold standard." Future studies that determine the criterion standard by triage providers might yield different results.

Although our initial study indicates that triage personnel should be able to consistently categorize patients using the recommended values for chief complaints, additional work will be needed to more fully evaluate the Frontlines of Medicine recommendations, the effectiveness of data collection systems, how to best analyze the data, and how to present them usefully to public health authorities. Some may criticize this article for providing

unverified results, and the Frontlines Project team certainly encourages efforts to validate the triage report data elements and recommended codified chief complaint values prospectively. Over time, the Frontlines recommendations may require modification according to such study. It may be reasonable to consider posting current and future versions of the Frontlines recommendations for reporting and coding structures on additional Web sites, such as the *Annals of Emergency Medicine* Web site, as a resource for future research.

A potential addition to be considered in the future is the creation of a Frontlines definition for a standardized structure for an emergency diagnosis and disposition report. If integrated with the recommended triage report described here, a disposition report would allow for the creation of a scalable emergency medicine encounter registry that could be used for quality initiatives, health policy planning, medical research, and other purposes in addition to surveillance.

Evaluation of the Frontlines triage surveillance report should proceed in accordance with updated guidelines recently published by the CDC.[26] We hope that the Frontlines of Medicine Project can rapidly contribute to the nation's safety from chemical and biological terrorism and other public health threats, including emerging infections. This important focus will allow the health care industry to move toward a vision of an integrated national emergency medicine community rather than a series of islands operating independently. Moreover, we hope that this ongoing process will continue to foster a spirit of collaboration to embrace a perhaps unprecedented opportunity to improve the public health information infrastructure in the United States and other nations.

Members of the Frontlines Work Group: Russ Brown, MS, Infinity HealthCare, Inc., Mequon, WI; William H. Cordell, MD, Department of Emergency Medicine, Indiana University School of Medicine, Indianapolis, IN; Craig Feied, MD, Department of Emergency Medicine, Washington Hospital Center, Washington, DC; Christopher W. Felton, MD, Emergency Department, Community Memorial Hospital, Menomonee Falls, WI; Michael Gillam, MD, Department of Emergency Medicine, Evanston Hospital, Evanston, IL; Jonathan Handler, MD, Division of Emergency Medicine, Northwestern University, Chicago, IL; Brian Keaton, MD, Department of Emergency Medicine, Summa Health System, Akron, OH; John C. Moorhead, MD, MS, Department of Emergency Medicine, Oregon Health and Science University, Portland, OR; Mark S. Smith, MD, Department of Emergency Medicine, Washington Hospital Center, Washington, DC; Jonathan Teich, MD, Emergency Medicine Residency Program, Brigham and Women's Hospital, Boston, MA; Joseph Waeckerle, MD, Department of Emergency Medicine, University of Missouri at Kansas City School of Medicine, Kansas City, MO.

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Edward N. Barthell, Christopher W. Felton, and Russ Brown are employees and shareholders of Infinity HealthCare, which markets networked emergency medicine information systems under the name EMSystem. William H. Cordell is a Strategic Advisor for New Wave Software, Inc. Craig Feied and Mark S. Smith are founders of and Jonathan Handler is the director of Development of the National Center for Emergency Medical Informatics. Dennis G. Cochrane is an employee of Emergency Medical Associates, which markets an emergency department information system under the name EDIM.

Reprints not available from the authors.

Address for correspondence: Edward N. Barthell, MD, MS, Infinity HealthCare, Inc., 1035 W. Glen Oaks Lane, Suite 101, Mequon, WI 53092; 414-290-6700, fax 414-290-6781; E-mail ebarthell@infinity-healthcare.com.

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